REMARKS

Reconsideration of the application in view of both the above amendment and the following remarks is requested.

The Examiner rejects claims 1-3 under 35 U.S.C. §112, ¶2 as being indefinite insofar as the use of the term "such as" in independent claim 1 leaves unclear whether the listed ailments are claim elements. The indefinite language "such as" has been replaced with "resulting from," which language from independent claim 4 the Examiner has raised no similar objection to. The claim as so amended is believed to now particularly point out and distinctly claim these ailment elements. Claims 1-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,164,398 issued November 17, 1992 to Sims *et al.* (hereinafter "Sims"). Independent claims 1 and 4 have been amended so that the compositions comprise active ingredients wherein those active ingredients "consist of" carbetapentane tannate and guaifenesin. Applicants believe that the claims as so amended distinguish over the cited reference.

Sims discloses ibuprofen-antitussive formulations, which Sims concedes to be generally known in the art (column 1, line 21-27). For the treatment of pain and inflammation and the relief of cough and cold symptoms, Sims *specifically* commends formulations that combine the single (S) enantiomer of ibuprofen with an antitussive, and "optionally" an expectorant. (column 1, lines 30-68 – column 2, lines 1-15). Sims discloses that the antitussive may be, *inter alia*, carbetapentane, or various salts of antitussives, and that the *optional* expectorant may be, *inter alia*, guaifensesin. Yet,

nothing in Sims suggests the claimed combination of carbetapentane tannate and guaifenesin. As the Examiner concedes, "Sims *et al.* do not exemplify a composition containing guaifenesin and carbetapentane." More accurately, Sims does not exemplify *any* composition containing *either* guaifenesin or carbetapentane, let alone *both* in combination. In fact, not one of Sims' exemplifying formulations (*Examples* 1-7) contains an expectorant! Each *Example* discloses the (S)-ibuprofen enantiomer in combination with an antitussive—not one of which is carbetapentane.

The failure of the reference to even remotely suggest the claimed combination of actives is not surprising, since the teaching of Sims *as a whole* is directed to the benefits of combining the single ibuprofen enantionmer with an antitussive generally. As Sims explains:

> "The utilization of (S)-ibuprofen in an analgesic/antitussive combination offers significant advantages over the combination of racemic ibuprofen with an antitussive. (S)-ibuprofen provides a faster onset of pain relief and an enhanced degree of relief compared to racemic ibuprofen. **These benefits are increased in an (S)-ibuprofen/antitussive combination as the antitussive may potentiate the action of the (S)-ibuprofen.** This has not heretofore been observed because the art has not proposed the combination of the (S)-ibuprofen enantiomer, absent (R)-ibuprofen, with an antitussive. **Furthermore the antitussive also may potentiate the duration of the analgesic and anti-inflammatory response.** The presence of the (R)-ibuprofen may blur the potentiated effect." (column 2, lines 46-59, emphasis added).

Clearly, based on the reference's teachings *as a whole*, the artisan having studied Sims would glean an appreciation for the synergy that might attend (S)-ibuprofen / antitussive formulations. But, nothing in Sims would suggest to the artisan the favorability of abandoning Sims' analgesic component, and combining the specific antitussive, carbetapentane, with the specific expectorant, guaifensin. Afterall, Sims *only* instructs

that expectorants—in general, not guaifenesin particularly—may be added "optionally." (column 1, lines 30-68 – column 2, lines 1-15). Compared to its teachings *as a whole*, Sims' entirety of instruction regarding expectorants so marginalizes their import as to make their mention seem an insignificant tangent:

> "Expectorants are useful in relieving upper chest congestion associated with the common cold and flu." (column 1, lines 19-20).
>
> "The amount of expectorant useful in the practice of the present invention may vary from about 100 mg to 1000 mg per daily dosage." (column 3, lines 35-38).

These meager disclosures hardly commend the claimed combination of actives, and the abandonment of Sims' (S)-ibuprofen. And, failing that *specific* suggestion, Sims does not render the instant claims obvious.

The Examiner asserts a contrary opinion, suggesting that the claimed combination would have been obvious "since Sims suggests this combination in the instant forms." Yet, as earlier noted herein, none of Sims' *Examples* utilize either active ingredient, or any expectorant. And, in the course of an obviousness inquiry the Examiner cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to thereby deprecate the claimed invention. In re Fine, 837 F.2d 1071, 1075 (Fed.Cir.1988). The Examiner further asserts that "it is obvious to a skilled artisan to remove the analgesic (used for the treatment of inflammation) if the symptoms do not require an anti-inflammatory." This assertion directly conflicts with Sims itself:

> "The composition and methods of the present invention may be used to treat pain and inflammation, or pain alone or inflammation alone where only one is present, along with the treatment of cough and cold symptoms." (column 2, lines 16-19).

Clearly, one skilled in the art seeking to treat pain, *or* inflammation, *or* cough, *or* cold, *or* any combination thereof, would rely on the Sims' formulation as a whole, rather than reformulate Sims in light of isolated symptoms. Moreover, the Examiner's proposed modification, which would have the artisan "remove the analgesic," would render Sims unfit for its intended purpose, which, as its *Abstract* informs, is "the treatment of pain and inflammation." Modifications that would render the prior art reference inoperable for its intended purpose are inappropriate for obviousness analyses. In re Gordon, 733 F.2d 900, 902 (Fed Cir. 1984). *Accord* In re Fritch, 972 F.2d 1260, 1265-66, fn. 12 (Fed. Cir. 1992). Therefore, the Examiner's proposed modification would not have been an obvious one.

The rejection fails to cite motivation because such motivation is found only through resort to impermissible hindsight and reference to the disclosure of the instant invention. The reference does not teach or suggest the claimed active ingredient combination, and the rejection essentially marginalizes that combination as being obvious to try. However, "[p]atentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. § 103(a). Whether a particular modification / combination might be "obvious to try" is not a legitimate test of patentability. In re Geiger, 815 F.2d 686, 688 (Fed. Cir. 1987).

The specification's disclosure is rife with antecedent support for the instant amendment to the language of claims 1 and 4. Indeed, from its very beginning the specification conceives that the invention is the novel combination of only two active ingredients, *specifically* carbetapentane tannate and guaifenesin. See page 2, lines 1-2

under *Field of Invention* and page 3, lines 16-18 under *The Invention.* Additionally, the use of only carbetapentane tannate and guaifenesin, as active ingredients, is taught by the disclosed embodiments. See pages 4 and 5 and the first two ingredients listed under *Example 1* and *Example 2* respectively.

In view of the foregoing, Applicants submit that the instant application is in condition for allowance, and they therefore request its prompt passage to issue.

It is believed that no fee is due. However, if any fee is due it should be charged to Deposit Account No.: 03-0678.

CERTIFICATE OF MAILING

Deposit Date: November 21, 2002

I hereby certify that this paper and the attachments hereto are being deposited today with the U.S. Postal Service with sufficient postage as First Class Mail to Addressee, under 37 CFR 1.8, on the date indicated above addressed to:

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11/21/02

Raymond E. Stauffer, Esq. Date

#161403 v1 - amendment & remarks

Respectfully submitted,

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